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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,464	03/24/2006	Michael Zarkh	B-5930PCT 623371-6	9272
35437 7590 03/02/2009 MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO ONE FINANCIAL CENTER BOSTON, MA 02111				
EXAMINER				
CARTER, AARON W				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,464

Applicant(s)

ZARKH ET AL.

Examiner

AARON W. CARTER

Art Unit

2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21, 24 and 26 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-18, 21, 24 and 26 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 24 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the primary centerline" in line 6. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. The Federal Circuit¹, relying upon Supreme Court precedent², has

¹ *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

² *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

indicated that a statutory “process” under 35 U.S.C. 101 must (1) be tied to a particular machine or apparatus, or (2) transform a particular article to a different state or thing. This is referred to as the “machine or transformation test”, whereby the recitation of a particular machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility (See *Benson*, 409 U.S. at 71-72), and the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity (See *Flook*, 437 U.S. at 590”). While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform an article nor are positively tied to a particular machine that accomplishes the claimed method steps, and therefore do not qualify as a statutory process.

Claims 2-18, 21 and 24 are rejected by the virtue of their dependency upon claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by USPN 2004/0260175 to Florent et al. (“Florent”).

As to claim 26, Florent disclose a system for three-dimensional reconstruction (3DR) of a single blood vessel using a plurality of two-dimensional images comprising:

a display for displaying a first image of a vascular network and a second image of a vascular network, and a three-dimensional reconstruction of a vessel (*Fig. 5, element 54 and paragraph 39*);

input means for receiving input for identifying a vessel of interest on the first image and for identifying the vessel of interest on the second image (*Fig. 5, elements 55 and 56, paragraph 39 and 31*);

a processor arranged to operate one or more application programs (*paragraph 39, wherein the processor disclosed it can be argued that any processor is arranged to operate one or more application programs regardless of the programs instruction. The claims language is vague as to whether the processor is configured with the following instructions or if the processor merely needs to be capable of operating a program with instruction. The Examiner will interpret the language as the later and as a result the computer instruction would not be given weight since they do not limit the structure of the processor or any other structure disclosed in the claim*) comprising computer instructions for:

tracing the edges of the vessel of interest including eliminating false edges of objects visually adjacent to the vessel of interest;

determining substantially precise radius and densitometry values along the vessel;

tracing the edges of the vessel of interest in the second image, including eliminating false edges of objects visually adjacent to the vessel of interest;

determining substantially precise radius and densitometry values along the vessel of interest in the second image;

determining a three dimensional reconstruction of the vessel of interest; and
determining fused area measurements along the vessel.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 7-10, 12, 15, 17, 18, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 6,301,498 to Greenberg et al. ("Greenberg") (already of record) in view of US 2004/0171932 to Raman et al. ("Raman").

As to claim 1, Greenberg discloses a method for three-dimensional reconstruction (3DR) of a single tubular organ using a plurality of two-dimensional images comprising:

Obtaining a first image of a vascular network (*column 6, lines 15-29*);

Identifying on the first image a vessel of interest (*column 10, lines 46-63, wherein a vessel of interest is identified*);

Tracing the edges of a vessel of interest including eliminating false edges of objects visually adjacent to the vessel of interest (*column 10, lines 46-63, wherein the boundaries of a vessel of interest are identified corresponding to tracing the edges*);

Determining substantially precise radius and densitometry values along the vessel (*column 5, lines 46-57, wherein the densitometry values are used to determine the thickness of an artery corresponding to a radius of the vessel*);

Obtaining a second image of the vascular network (*column 6, lines 15-29*);

Identifying on the second image the vessel of interest (*column 10, lines 46-63, wherein a vessel of interest is identified*);

Tracing the edges of a vessel of interest including eliminating false edges of objects visually adjacent to the vessel of interest (*column 10, lines 46-63, wherein the boundaries of a vessel of interest are identified corresponding to tracing the edges*);

Determining substantially precise radius and densitometry values along the vessel of interest in the second image (*column 5, lines 46-57, wherein the densitometry values are used to determine the thickness of an artery corresponding to a radius of the vessel*);

Determining a three dimensional reconstruction of the vessel of interest (*column 5, lines 10-45*); and

Determining a fused area measurement along the vessel (*column 11, line 32 - column 12, line 2, wherein the lumen functions are fused corresponding to fused area measurements*).

Greenberg does not disclose expressly displaying the first and second image or receiving input for identifying on the first or second image the vessel of interest.

However, Raman discloses displaying images to a user and allowing the user to mark or identify vessels of interest in the images (*paragraph 17*).

Greenberg & Raman are combinable because they are from the same art of image processing.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the technique of displaying images to a user and allowing the user to mark or identify vessels of interest in the images, as taught by Raman, with the process of 3DR disclosed by Greenberg.

The suggestion/motivation for doing so would have been to provide the well know advantages of human assistance or intervention in image processing.

Therefore, it would have been obvious to combine Greenberg with Raman to obtain the invention as specified in claim 1.

As to claim 2, the combination of Greenberg and Raman discloses the method according to claim 1, wherein the vessel of interest is selected from the group consisting of: an artery, a vein, a coronary artery, a carotid artery, a pulmonary artery, a renal artery, a hepatic artery, a femoral artery, a mesentric artery, and any other tubular organ (*Greenberg, Abstract, "artery"*).

As to claim 3, the combination of Greenberg and Raman discloses the method according to claim 1, further comprising determining a centerline, comprising a plurality of centerline points (*Raman, paragraph 17*).

As to claim 4, the combination of Greenberg and Raman discloses the method according to claim 1, wherein the fused area measurements are obtained using a fusion of diameter and cross section-densitometry derived measurements (*Greenberg, column 5, lines 46-57 and column 11, line 32 - column 12, line 2*).

As to claim 7, the combination of Greenberg and Raman discloses the method according to claim 1, wherein the input for identifying the vessel of interest comprises three points: a first point to mark the stenosis general location, a second point proximal to the stenosis, and a third point distal to the stenosis (*Raman, paragraph 17*).

As to claim 8, the combination of Greenberg and Raman disclose the method according to claim 1, wherein the input for identifying the vessel of interest comprises markers for two points for at least one of the first and second images, wherein one of the two points is anywhere proximal to the stenosis and the other point is anywhere distal to the stenosis (*Raman, paragraph 17*).

As to claim 9, the combination of Greenberg and Raman disclose the method according to claim 1, wherein the markers comprise two points for the first image and one point for the second image, wherein one of the two points is anywhere proximal to the stenosis and the other point is anywhere distal to the stenosis and wherein one point is an anchor point identified automatically on the first image (*Raman, paragraph 17*).

As to claim 10, the combination of Greenberg and Raman disclose the method according to claim 1, Wherein elimination of false edges comprises ignoring one or more bubbles adjacent the vessel of interest (*Greenberg, column 10, lines 46-63, wherein anything outside the vessel of interests boundaries is ignored*).

As to claim 12, the combination of Greenberg and Raman disclose the method according to claim 1, Wherein elimination of false edges comprises detecting and/or eliminating one or more bumps along the vessel of interest (*Greenberg, column 10, lines 46-63, wherein anything outside the vessel of interests boundaries is ignored*).

As to claim 15, the combination of Greenberg and Raman disclose the method according to claim 1, wherein determining densitometry values comprises subtracting a background influence (*Greenberg, column 6, line 54 – column 7, line 7*).

As to claim 17, the combination of Greenberg and Raman disclose the method according to claim 1, further comprising determining healthy vessel dimensions using an iterative regression over a healthy portion of the vessel of interest (*Greenberg, column 10, lines 45-63*).

As to claim 18, the combination of Greenberg and Raman disclose the method according to claim 17, wherein each iteration comprises a compromise between a pre-defined slope and a line that follows healthy data (*Greenberg, column 10, lines 45-63*).

As to claim 24, the combination of Greenberg and Raman disclose the method according to claim 1, further comprising displaying quantitative analysis of the vessel of interest including cross-section area graph and/or lesion analysis measurements (*Greenberg, Figs. 5e, 13 and 14*).

As to claim 26, please refer to the rejection of claim 1 above.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON W. CARTER whose telephone number is (571)272-7445. The examiner can normally be reached on 8am - 4:30 am (Mon. - Fri.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Werner can be reached on (571) 272-7401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron W Carter/
Primary Examiner, Art Unit 2624